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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,355	04/23/2007	Robert K. Gieseler	021069.3	7391

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EXAMINER	
HILL, KEVIN KAI	
ART UNIT	PAPER NUMBER
1633	
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07/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,355	GIESELER ET AL.	
	Examiner	Art Unit	
	KEVIN K. HILL	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-10,13,15,16,20-24,26-28,37-44,50,52-65,67-71,73 and 75-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,6-10,13,15,16,20-24,26-28,37-44,50,52-65,67-71,73 and 75-81.

Election/Restrictions

1. **Restriction is required under 35 U.S.C. 121 and 372.**

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 2, 6-10, 13, 20-24, 26-28, 37-44, 50, 52-53, 55-59, 75-79 and 81, drawn to a method of delivering an active agent to a reservoir cell of a mammal, the method comprising administering to the mammalian subject a lipid-active agent complex comprising the active agent and at least one targeting ligand, wherein the reservoir cell is infected with, or susceptible to infection with, an infectious agent.

Group II, claim(s) 60-65, 67-71, 73 and 80, drawn to a targeting system for delivery of an active agent to a reservoir cell, the system comprising a lipid-active agent complex and a targeting ligand on the outer surface of the lipid-active agent complex.

2. **The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1** because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature' means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, WO 98/07408 (*of record in IDS) discloses a method of delivering an active agent to a reservoir cell of a mammal, the method comprising administering to the mammalian subject a liposome composition comprising DOTAP and at least one cholesterol or cholesterol derivative, a biologically active agent, i.e. nucleic acid DNA, and a targeting ligand. Thus, Claim 1 does not contribute over the prior art.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the Group I method may be practiced with structurally distinct delivery systems comprising distinctly different active agents, e.g. a gene-silencing RNA molecule, a protein-coding DNA molecule, or an apoptosis inhibitor, as evidenced by the claims.

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a

serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, Applicant must indicate which of these claims are readable upon the elected invention.

Should Applicant traverse on the ground that the inventions are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. **A species restriction is required under 35 U.S.C. 121 and 372.** This application contains claims directed to more than one species of active agents. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single active agent species.

The active agent species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple compounds that are structurally distinct and unrelated molecules that are not obvious variations of each other because one skilled in the art does not expect a gene-silencing RNA molecule to achieve the same biological effect as an antibacterial drug, for example. Each of the agent species confers a unique, non-obvious, distinctly different technical feature onto the targeting system that will directly impact the bioavailability, toxicity or bioactivity of the system. Given the breadth of the claimed, unrelated structures, a search for all possible species at each of the recited active agents imposes an exceptional burden on the Office. As the technical feature linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single active agent species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner: Claims 1, 52, 60, 64, 75-76 and 80-81, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 1, 52, 60, 64, 75 and 81.

4. **A species restriction is required under 35 U.S.C. 121 and 372.** This application contains claims directed to more than one species of targeting ligands. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive

concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single targeting ligand species.

The targeting ligand species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple compounds that are structurally distinct and unrelated molecules that are not obvious variations of each other because each targeting ligand specifies the delivery system to a distinctly different cell type, for example. Each of the targeting ligand species confers a unique, non-obvious, distinctly different technical feature onto the targeting system that will directly impact the bioavailability, toxicity or bioactivity of the system. Given the breadth of the claimed, unrelated structures, a search for all possible species at each of the recited targeting ligands imposes an exceptional burden on the Office. As the technical feature linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single targeting ligand species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner: Claims 1, 52, 60, 64, 75-76 and 80-81, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 1, 60, 75 and 81.

5. **A species restriction is required under 35 U.S.C. 121 and 372.** This application contains claims directed to more than one species of infectious agents. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single infectious agent species.

The infectious agent species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple infectious agents that are structurally distinct and biologically unrelated agents that are not obvious variations of each other because those of ordinary skill in the art would not consider Ebola virus to be equivalent to Mycobacterium (a parasite), for example. Given the breadth of the claimed, unrelated infectious agents, a search for all possible species at each of the recited agents imposes an exceptional burden on the Office. As the technical feature linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single infectious agent species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner: Claims 6-8 and 76, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 1, 52 and 75 are generic.

6. **A species restriction is required under 35 U.S.C. 121 and 372.** This application contains claims directed to more than one species of reservoir cells. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single reservoir cell species.

The reservoir cell species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple reservoir cells that are structurally and biologically distinct and are not obvious variations of each other because each reservoir cell is subject to

specific targeting via a specific targeting ligand on the delivery system, for example. Given the breadth of the claimed reservoir cells, a search for all possible species at each of the recited agents imposes an exceptional burden on the Office. As the technical feature linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single reservoir cell species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner: Claims 38-40, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claims 1, 52, 60, 64, 75-76, and 80-81are generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP §809.02(a).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to KEVIN K. HILL whose telephone number is (571)272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill/
Examiner, Art Unit 1633